

I. AMENDMENTS

AMENDMENTS TO THE CLAIMS

Cancel claims 57 and 61 without prejudice to renewal.

Please enter the amendments to claims 31, 40, 41, and 56, as shown below.

Please enter new claims 62-65, as shown below.

1-30 (canceled).

31. **(Currently amended)** A method for predicting the likelihood that a human colon cancer patient will respond to treatment with an ErbB1 inhibitor, the method comprising:

a) ~~assaying a determining the~~ normalized level of a predictive RNA ~~transcript transcripts~~ in a sample comprising ErbB1-expressing cancer cells obtained from said patient, wherein the predictive RNA transcript transcripts ~~are is~~ the transcript of laminin gamma 2 (LAMC2) ~~or glypican 3 (GPC3) ; and~~

b) analyzing the normalized level of the LAMC2 transcript so as to predict the likelihood of response of the patient to treatment with an ErbB1 inhibitor based on the normalized level of the LAMC2 transcript wherein a higher normalized level of LAMC2 RNA transcript indicates that the patient will show a decreased likelihood of response to treatment with an ErbB1 inhibitor, and a higher normalized level of GPC3 RNA transcript indicates that the patient will show an increased likelihood of response to treatment with an ErbB1 inhibitor , wherein the normalized level of LAMC2 RNA transcript correlates with patient response to treatment with an ErbB1 inhibitor, wherein the ErbB1 inhibitor interacts with an ErbB1 receptor.

32.-34. (canceled)

35. (Previously presented) The method of claim 31 wherein said sample is a tissue sample.

36. (Previously presented) The method of claim 35 wherein the tissue sample is fixed, paraffin-embedded, or fresh, or frozen.

37. (Previously presented) The method of claim 35 wherein the tissue sample is derived from fine needle, core, or other types of biopsy.

38. (Previously presented) The method of claim 31 further comprising the step of preparing a report

comprising a statement whether the patient is likely to respond to treatment with an ErbB1 inhibitor.

39. (canceled)

40. (**Currently amended**) A method comprising ~~treating~~ administering to a human patient an effective amount of an ErbB1 inhibitor that interacts with an ErbB1 receptor, wherein the patient has been diagnosed with an ErbB1-expressing colon cancer and determined to have elevated normalized expression of predictive RNA transcripts of GPC3 gene in said cancer, or decreased a normalized level of expression of predictive RNA transcripts of a laminin gamma 2 (LAMC2) LAMC2 RNA transcript that indicates that the patient will likely respond to treatment with an ErbB1 inhibitor gene, with an effective amount of an ErbB1-inhibitor.

41. (**Currently amended**) The method of claim 31 wherein the level of ~~predictive~~ the LAMC2 RNA transcript is determined using an array comprising polynucleotides hybridizing to a LAMC2 gene ~~the following genes: LAMC2 and GPC3; immobilized on a solid surface.~~

42. (Previously presented) The method of claim 41 wherein said polynucleotides are cDNAs.

43. (Previously presented) The method of claim 42 wherein said cDNAs are about 500 to about 5000 bases.

44. (Previously presented) The method of claim 41 wherein said polynucleotides are oligonucleotides.

45. (Previously presented) The method of claim 44 wherein said oligonucleotides are about 20 to 80 bases long.

46. (Previously presented) The method of claim 45 wherein the array comprises about 330,000 oligonucleotides.

47. (Previously presented) The method of claim 41 wherein said solid surface is glass.

48.-50. (canceled)

51. (Previously presented) The method of claim 35, wherein RNA is isolated from colon cancer cells present in a fixed, paraffin-embedded tissue by a procedure comprising:

- (a) incubating one or more sections of said fixed, paraffin-embedded tissue at a temperature of about 56 °C to 70 °C in a lysis buffer, in the presence of a protease, without prior dewaxing, to form a lysis solution;
- (b) cooling the lysis solution to a temperature where the paraffin solidifies; and
- (c) isolating the RNA from said cooled lysis solution.

52. (Previously presented) The method of claim 31 further comprising the use of a kit comprising one or more of (1) extraction buffer/reagents for extracting mRNA from a sample and protocol; (2) reverse transcription buffer/reagents and protocol; and (3) qPCR buffer/reagents and protocol suitable for performing the method of claim 31.

53.-55. (canceled)

56. **(Currently amended)** A method of using the expression level of a laminin gamma 2 (LAMC2) gene ~~LAMC2 or GPC3 genes~~ to predict the likelihood that a patient diagnosed with an ErbB1-expressing colon cancer will respond to treatment with an ErbB1 inhibitor, ~~the method~~ comprising [(a)] analyzing a normalized level of a LAMC2 transcript to as to predict ~~predicting~~ a decreased likelihood of response if the normalized expression level of LAMC2 gene is elevated in said patient ~~and~~

~~(b) — predicting an increased likelihood of response if the expression level of GPC3 gene, is elevated in said patient.~~

57.-58. (Cancelled)

59. (Previously presented) The method of claim 41, wherein said polynucleotides comprise modified and unmodified polynucleotides.

60. (Previously presented) The method of claim 31, further comprising determining the normalized level of one or more predictive RNA transcripts in said sample, wherein the predictive RNA transcript is the transcript of one or more genes selected from the group consisting of: Bak; Bclx; BRAF; BRK; Cad17; CCND3; CCNE1; CCNE2; CD105; CD9; COX2; DIABLO; ErbB3; EREG; FRP1; GUS; HER2; HGF; ID1; ITGB3; PTPD1; RPLPO; STK15; SURV; TERC; TGFB2; TITF1; XIAP; CA9; CD134; CD44E; CD44v3; CD44v6; CDC25B; CGA; DR5; GRO1; KRT17; P14ARF; PDGFB; PLAUR; PPARG; RASSF1; RIZ1; Src; TFRC and UPA, wherein an increased normalized level of the predictive RNA transcript of one or more of CA9; CD134; CD44E; CD44v3; CD44v6; CDC25B; CGA; DR5; GRO1; KRT17; P14ARF; PDGFB; PLAUR; PPARG; RASSF1; RIZ1; Src;

TFRC and UPA, indicates that the patient will show a decreased likelihood of response to treatment with an ErbB1 inhibitor, and an increased normalized level of the predictive RNA transcript of one or more of Bak; Bclx; BRAF; BRK; Cad17; CCND3; CCNE1; CCNE2; CD105; CD9; COX2; DIABLO; ErbB3; EREG; FRP1; GUS; HER2; HGF; ID1; ITGB3; PTPD1; RPLPO; STK15; SURV; TERC; TGFBR2; TITF1; and XIAP indicates that the patient will show an increased likelihood of response to treatment with an ErbB1 inhibitor.

61. (Cancelled)

62. (New) The method of claim 31, further comprising determining the normalized level of a predictive RNA transcript of Kirt17 in the sample.

63. (New) A method for predicting the likelihood that a human cancer patient will respond to treatment with an ErbB1 inhibitor, the method comprising:

a) assaying A normalized level of a predictive RNA transcript in a sample comprising ErbB1-expressing cancer cells obtained from said patient, wherein the predictive RNA transcript is a laminin gamma 2 (LAMC2) RNA transcript;

b) analyzing the normalized level so as to predict a likelihood of response to treatment with an ErbB1 inhibitor, wherein the normalized level of the LAMC2 RNA transcript correlates with patient response to treatment with an ErbB1 inhibitor, and wherein the ErbB1 inhibitor interacts with an ErbB1 receptor.

64. (New) A method comprising administering to a human patient an effective amount of an ErbB1 inhibitor that interacts with an ErbB1 receptor, wherein the patient has been diagnosed with an ErbB1-expressing cancer and has been determined to have a normalized level of a laminin gamma 2 RNA transcript that indicates that the patient will likely respond to treatment with an ErbB1 inhibitor.

65. (New) A method of using the expression level of a laminin gamma 2 (LAMC2) gene to predict the likelihood that a patient diagnosed with an ErbB1-expressing cancer will respond to treatment with an ErbB1 inhibitor, the method comprising analyzing a normalized level of a LAMC2 transcript to as to predict a decreased likelihood of response if the normalized expression level of LAMC2 gene is elevated in said patient.